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Original Research

Pharmaceutical care improves medication adherence and quality of life in type 2 diabetes mellitus

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Abstract

Aims: This study aimed to evaluate whether pharmacotherapeutic follow-up in patients with T2DM in primary care interferes in metabolic control, cardiovascular risk, medication adherence and quality of life. **Methods:** A prospective clinical study was conducted at two Primary Health Units in Vitória, Espírito Santo, Brazil with 75 patients with T2DM between 40 and 70 years old. The parameters of metabolic control evaluated included fasting blood glucose, HbA1c, triglyceride/HDL-c and total cholesterol/HDL-c ratio. The cardiovascular risk was calculated based on the Framingham risk score. Adherence to medication was measured using the Brief Medication Questionnaire and quality of life was evaluated by applying the World Health Organization Quality of Life-Bref. **Results:** After the follow-up, there was a significant decreasing in cardiovascular risk (p=0.048) and total cholesterol/HDL-c ratio (p=0.024) and a discrete improvement in fast glucose and HbA1c levels. The quality of life scores increased for all domains (p<0.0001) and the treatment adherence also improved with 12.00% of the patients classified as low adherence in the final time, against 41.33% before the meetings. **Conclusion:** These results show the proposed pharmacotherapeutic follow-up influenced positively cardiovascular risk, adherence to therapy and quality of life in all domains, and, therefore, may contribute to delay the onset of the main chronic complications of the disease.

Keywords: Pharmaceutical care; cardiovascular risk; medication adherence; quality of life

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INTRODUCTION

Type 2 diabetes mellitus (T2DM) is one of the four most prevalent chronic noncommunicable diseases (NCDs), responsible for 1.6 million deaths globally.[1] The central events of the pathophysiology of T2DM, insulin resistance and pancreatic beta-cell dysfunction progressively evolve, which can be accelerated by inadequate therapy or lifestyle.[2] A national-based prevalence study conducted in Brazil revealed poor glycemic control among individuals with type 2 diabetes, with 73% of individuals with higher levels of glycated hemoglobin than recommended for disease control (desirable value ≤ 7%),[3] showing the need to investigate possible obstacles to successful therapy.

The hyperglycemic environment induces the formation of cell-damaging products, contributing to the onset of late complications of diabetes - macro and microvascular complications.[4] Due to the chance of developing these complications, the risk of death from cardiovascular problems is higher in adults with diabetes than adults without diabetes, in addition to increasing other macrovascular events such as stroke and amputations,[5] which compromise the productivity, quality of life and survival of individuals.[6,7]

The control of hyperglycemia requires the patient's active participation in adherence to often complex drug regimens and nonpharmacological measures, which involve changes in diet and physical exercise.[8] Therefore, health actions require good communication to ensure that the patient understands the natural progression of the disease, and that the review of pharmacotherapy and the adjustment of treatment are

intrinsic to treatment of T2DM.[9]

Pharmaceutical care services can be used as a strategy to overcome these barriers, through various tools, promoting the rational use of drugs and medication adherence, seeking to improve the quality of life of patients.[10] Studies evaluating pharmaceutical care programs in patients with T2DM in Brazil at public health system show a significant reduction in the glycemic index,[11] illustrating its efficiency in controlling the disease and preventing the main complications.

Once the treatment of T2DM comprises the continuous use of polypharmacy as a characteristic, this study aimed to investigate whether pharmacotherapeutic follow-up in patients with T2DM with and without insulin therapy interferes in medication adherence, quality of life, and metabolic control.

METHODS

Study design and population

This prospective clinical study was conducted at two Primary Care Units in Vitória, Espírito Santo, Brazil. The recruitment and data collection took place between June 2016 and January 2018. This research was approved by the research ethics committee of the Center of Health Sciences from the Federal University of Espírito Santo by the number 29115014.7.0000.5060. An informed consent was obtained from all the human subjects' participants of the research and their privacy was respected.

The sample size was calculated on the basis of the following assumptions: use of the single-proportion formula with a 95% confidence level; 8% margin of error. A final sample size of 80 patients with type 2 diabetes between 40 and 70 years old was invited to participate. Patients diagnosed with cancer, autoimmune disease and acute infections or who had surgery less than six months before were not included. From the total of 80 patients, five subjects who did not complete the follow-up were excluded. The study was concluded with 75 patients as shown in the following flow chart (Figure 1).

Pharmacotherapeutic follow-up instrument and data collection

Pharmacotherapeutic follow-up was developed according to the model proposed by the Brazilian Ministry of Health,[12] performing meetings with patients every 2 months for 6 months. The model is structured in four stages, which include: introduction; data collection and problem identification; actions and solutions, and closing of the appointment. Following this query script, a therapeutic relationship with the patient was established at the first meeting to identify the patient's needs related to the medication, investigating the current state of each health problem, the correct use of the drugs prescribed

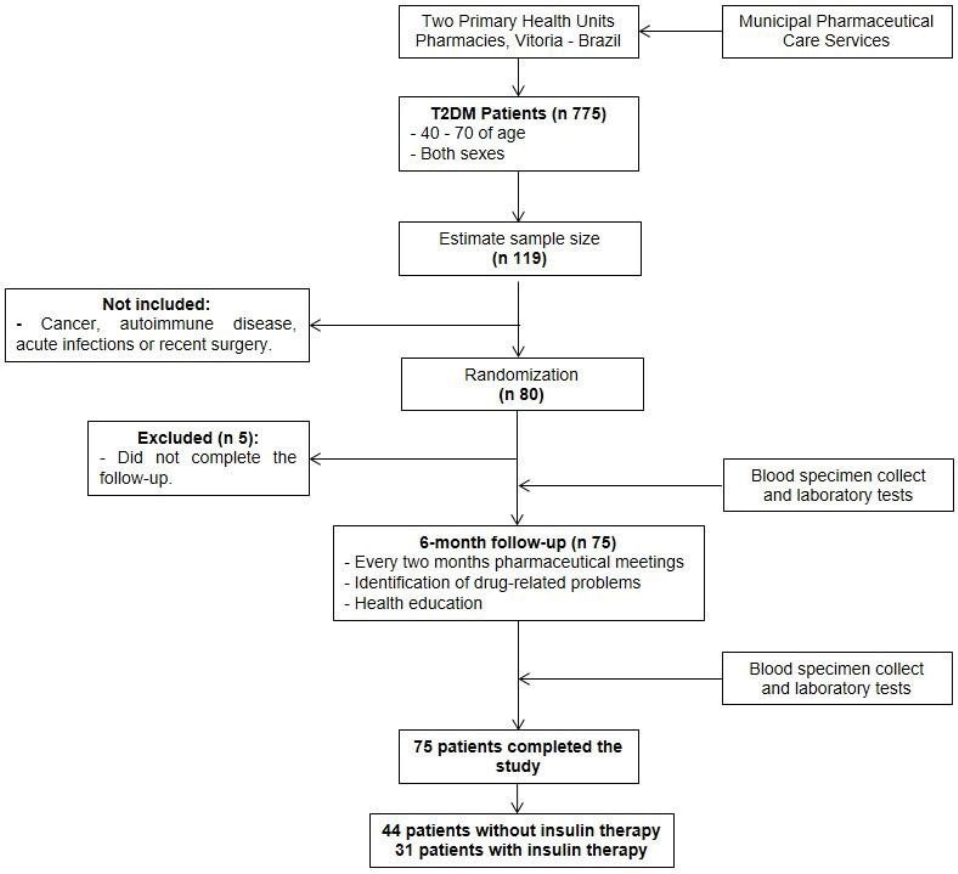

Figure 1. Flow chart of the recruitment process of people with diabetes and study design

and the existence of self-medication. Next, a plan of care was developed, guiding the function of each medication, health conditions, and lifestyle, providing support materials such as a daily dosing schedule and a daily self-monitoring book. Finally, strategies were agreed upon to facilitate the monitoring of the plan and space for additional doubts.

Data were analyzed as a total sample and stratified according to baseline and pos follow-up. The variables that could be influenced by pharmacotherapeutic follow-up were explored by comparing the results at baseline and after a 6month follow-up.

Medication adherence

To investigate the extent to which drug administration coincides with the therapy prescribed, the Brief Medication Questionnaire (BMQ), translated into Portuguese and validated, was applied.[13] The BMQ is composed of three screens that identify barriers to adherence regarding treatment regimens, patient beliefs and patient recall of medication treatment. The participants are classified into the following categories: adherence (no positive response in any domain), probable adherence (positive response in one domain), probable low adherence (positive responses in two domains) and low adherence (positive responses in all three). To evaluate the performance of individuals in each domain, the results were transformed into dichotomous variables. In this case, the occurrence of a positive response was sufficient for classification as nonadherent.

Quality of life

The abbreviated quality of life inventory proposed by the World Health Organization, the World Health Organization Quality of Life (WHOQOL-Bref), Portuguese version, was adopted for quality of life assessment. This form is composed of 26 questions divided into physical health, psychological health, social relationships, and environment, which follow the Likert scale (from 1 to 5, the higher the score, the better the quality of life).

Anthropometric and biochemical parameters

Some indicators were calculated from the anthropometric data to evaluate the users' clinical status. The patients' cardiovascular risk was assessed using the Framingham Risk Score. The biochemical parameters investigated were fasting glycemia, glycated hemoglobin, triglycerides/High-density lipoprotein cholesterol ratio and total cholesterol/High-density lipoprotein cholesterol ratio.

Statistical analysis

Data were analyzed with The Statistical Package for the Social Sciences (SPSS, Version 22 Inc., Chicago, IL, USA) and GraphPad Prism software, Version 5.0. The results were assessed using nominal/ordinal variables as frequencies (number and percentage) and continuous variables represented as mean ± standard deviation. Nominal/ordinal variables were compared by Chisquare test or Fisher's exact test. Paired Student *t*-test was applied for intragroup analysis, and unpaired Student *t*-test was applied between the groups without and with insulin therapy. Cohen's Kappa coefficient was used to measure the agreement of ordinal medication adherence scores between pre and post-follow-up. These results were interpreted according to the scale proposed by Landis and Koch (1977). *P* value < 0.05 was considered statistically significant.

RESULTS

This study was concluded with 75 patients with T2DM from two Primary Care Units. Individualized interventions were made, including home visits, health education, referral to specialized professionals, identification of adverse drug reactions, identification of the need for change in therapy or of inadequate dosage, incentive for adherence and information on the importance of adherence to nonpharmacological measures and self-monitoring. The sociodemographic information and risk factors obtained are shown in (Table 1). The mean age of these patients was 58.63 ± 9.28 years, of which 72% were females. Among them, 48% had secondary school education and were employed, unemployed and retired at a similar rate. The mean monthly income were 675.00 ± 543.00 dollars (US$) per month. Nearly 58.67% of the sample were married and most of them were brown.

Table1.Demographic characteristics and risk factors of the T2DM for the total sample (n=75)

	parameter	Grade	Total
Demographic characteristics	**Age (years)** (Mean ± SD)	-	58.63 ± 9.28
	Sex (N, %)	Female	54 (72.00)
		Male	21 (28.00)
	Occupation (N, %)	Employed	26 (34.67)
		Unemployed	23 (30.67)
		Retired	26 (34.67)
		Unlettered	2 (2.67)
	Education level (N, %)	Primary school	32 (42.67)
		Secondary school	36 (48.00)
		Bachelor or above	5 (6.67)
	Monthly income (US dollar) (Mean ± SD)	-	675.00 ± 543.00
	Marital status (N, %)	Single	14 (18.67)
		Married	44 (58.67)
		Divorced	6 (8.00)
		Widow/er	11 (14.67)
	Race (N, %)	Caucasian	27 (36.00)
		African American	15 (20.00)
		Brown	33 (44.00)
Risk factors	**Alcohol consumption** (N, %)	Yes	21 (28.00)
		No	54 (72.00)
	Cigarette consumption (N, %)	Yes	10 (13.33)
		No	65 (86.67)

SD: Standard deviation. N: Number. %: Percentage

From the distribution of risk factors and T2DM complications, one observes that most of the individuals do not consume alcohol (72%), are nonsmokers (86.57%) and present hypertension (77.33%). Regarding the duration of T2DM, the majority had diabetes for more than five years (69.33%) and most of the patients did not have microvascular complication (81.33%).

The results for the cardiovascular risk, anthropometric and biochemical parameters are organized in (Table 2). For the waist circumference parameter, the women showed higher mean values, with no statistical difference in both sexes after the follow-up. Cardiovascular risk and total cholesterol/HDL-c ratio showed differences after the pharmaceutical intervention. The fasting blood glucose and HbA_{1c} concentration had a little modification at the end of the appointments, without statistical significance. Likewise, TG/HDL-c ratio measurement did not show a statistical difference, although after the intervention it decreased largely.

The evaluation of the medication adherence showed an increase after the follow-up program, with a slight agreement in the pre and post follow-up evaluation, with 12.00% of the patients classified as having low adherence in the final time, against 41.33% with the same classification before the meetings (Figure 2-A), similar to studies assessing adherence to treatment in T2DM patients in which most of these individuals were classified as low adherence.[15]

To identify the barriers to medication treatment, BMQ domains were stratified as dichotomous variables, making it possible to observe the adherence profile among users (Figure 2-B). The regimen and belief domains had a significant increase after performing the pharmaceutical care. The recall for a barrier for medication treatment had the worst performance, with no difference after follow-up.

The assessment of the quality of life by comparing the groups before and after the follow-up showed an increase in the score for all domains (Table 3), which has been reported in the literature.[16-18] At the baseline, the physical domain was scored from 13.46 ± 2.37 to 15.39 ± 2.32 after follow-up (p<0.0001). For the psychological domain, the initial score was 14.23 ± 2.76 and it increased to 16.35 ± 2.32 (p<0.0001). The initial social relation score was 14.63 ± 2.66, and the final score was 16.83 ± 2.89 (p<0.0001). For the environmental domain at the beginning of the study, the score was 13.78 ± 1.88 and after follow-up 15.83 ± 2.63 (p<0.0001).

DISCUSSION

The main findings of this study show this pharmacotherapeutic follow-up model resulted in improvements in the adherence to medication, the quality of life and the decrease in cardiovascular risk in patients with T2DM. The rate of hypertension diagnosis was similar to that of a study conducted in Southeastern Brazil, in which 81.3% T2DM participants had hypertension.[19] Also, a high frequency of patients did not practice physical activity (64.38%), which is an essential part of the nonpharmacological approach that is inversely related to the development of T2DM, improving glycemic control and lipid profile.[20]

A 20-year follow-up study shows regular practice of physical activity showed capacity to reduce body weight, improve insulin

Table 2. Anthropometric comparison between T2DM patients at the baseline and after a 6-month follow-up

Parameter	Baseline	After a 6-month followup	p(a)
Waist circumference (cm) (Mean ± SD)	101.70 ± 12.36	101.60 ± 12.93	0.878
Female	102.60 ± 13.06	102.90 ± 13.58	0.573
Male	98.18 ± 8.25	97.05 ± 8.67	0.257
Framingham risk score (%) (Mean ± SD)	23.92 ± 16.19	21.18 ± 12.89	0.048*
Fasting blood glucose (mg/dL) (Mean ± SD)	157.0 ± 69.15	153.60 ± 65.33	0.480
HbA_1c (%(mmol/mol) (Mean ± SD)	7.9 ± 2.06 (63 ± 22.44)	7.8 ± 2.09 (66 ± 50.24)	0.407
TG/HDL-c ratio (Mean ± SD)	5.27 ± 7.08	4.01 ± 3.08	0.096
TC/HDL-c ratio (Mean ± SD)	4.44 ± 1.88	4.01 ± 1.52	0.024*

N: Number. %: Percentage. BP: Blood pressure. BMI: Body mass index. HbA_{1c}: Glycated hemoglobin. TG: Triglyceride. HDL-c: High-density lipoprotein cholesterol. TC: Total cholesterol. [(a)] Paired Student-t test. * Statistical significant difference (p<0.05)

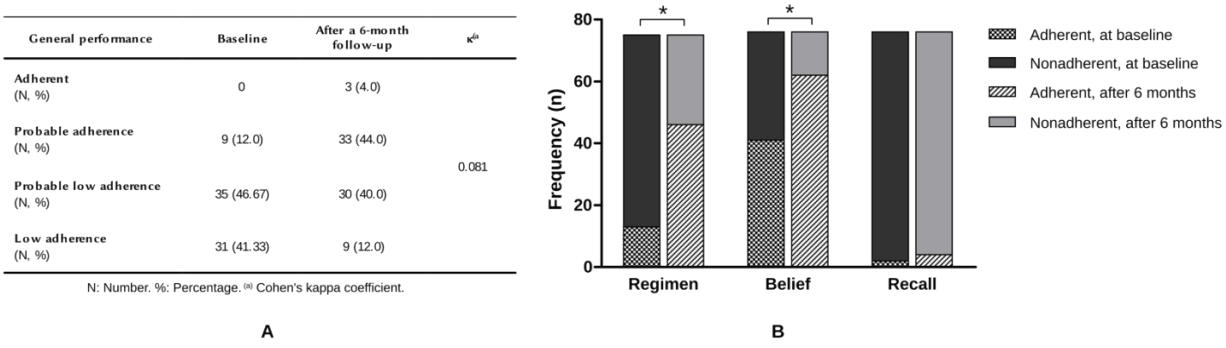

Figure 2. A: Evaluation of the general performance of adherence to therapy by application of the Brief Medication Questionnaire among T2DM at the baseline and after a 6-month follow-up. B: Dichotomous results of Brief Medication Questionnaire domains. *Statistical significant difference for Fisher's exact test between groups (p<0.05)

Table 3. Assessment of quality of life through the application of the WHOQOL - BREF questionnaire among T2DM patients at the baseline and after a 6-month follow-up

Domain	Baseline	After a 6-month follow-up	P[(a)]
Physical (Mean ± SD)	13.46 ± 2.37	15.39 ± 2.32	<0.0001*
Psychological (Mean ± SD)	14.23 ± 2.76	16.35 ± 2.32	<0.0001*
Social Relatioship (Mean ± SD)	14.63 ± 2.66	16.83 ± 2.89	<0.0001*
Environmental (Mean ± SD)	13.78 ± 1.88	15.83 ± 2.63	<0.0001*

sensitivity and normalize blood pressure.[21] Thus, it reinforces the importance of the practice of physical activity for the control of T2DM and hypertension, since the presence of other comorbidities further complicates the adherence, due to the increased number of medications and the need for patient recall.

The lack of difference for some of the metabolic parameters was reported in other studies in which glycated hemoglobin levels were not different after the pharmaceutical care program.[22,23] This result may be related to the short follow-up period, in addition to the fact that the follow-up program was not linked to a multi-professional team, which could be a strategy for metabolic control since diabetes is a complex disease that involves lifestyle changes, continuous monitoring, and treatment intensification. During the follow-up, nonpharmacological practices were not deepened, such as changes in diet and physical activity, which could positively influence these results.

Reduced risk of developing cardiovascular disease may be associated with a reduction in plasma LDL-cholesterol and HDL-cholesterol, which are variables used for estimating the score.[24] Neto et al., (2011), through a 36-month pharmacotherapeutic follow-up with elderly hypertensive and / or diabetic patients, revealed a reduction in the risk of developing cardiovascular diseases, indirectly improving the quality of life of these individuals. This decrease was also obtained after a 2-year pharmacotherapeutic follow-up,[26] and for 6 months in Brazil, which showed a reduction in risk after comparison with the control group and evaluation before follow-up.[27]

Adherence is a multidimensional phenomenon determined by the interaction of a set of factors that affect people's behavior and ability to follow treatment.[28] Frequent adherence difficulties in chronic diseases such as T2DM requiring long, complex and life-changing treatments in the general population are associated with a 50% nonadherence.[29]

The BMQ assesses medication adherence in three domains: regimen, belief and recall, which allows the approach of factors that hinder adherence, such as the amount of medication administered daily, the occurrence of adverse effects and confidence in the self-care practice. The dichotomous analysis showed increased adherence to the regimen and belief domains and absence of change in the recall domain at the end of the meetings. In this case, aging and the high proportion of patients with hypertension, related to polymedication, can be considered barriers to recall of medication treatment.

Among the strategies to improve adherence are education, better treatment regimens and better communication between physicians and other health professionals and patients.[30] The strategies provided by this study support the implementation of interventions directed to the patients' individual needs, facilitating the management by the health professional during the meetings, which may be related to the improvement in the adherence to medication. The close professional relationship built between the patient and the pharmacist must have improved the communication and the desire to reciprocate with positive results. In addition, patients' education is essential to achieve optimal outcome in the treatment of diabetes because it can enable patients to effectively engage in health management, promoting the self-management of their disease, and improving patients' compliance.[31]

The Brazilian Consensus on Pharmaceutical Care defined macro components of this practice that guarantee the rational use of drugs and adherence to treatment, improving the patients' quality of life,[32] as found in this study. Between its individual scores, the physical domain had a lower performance in both groups.

Souza et al. (1997) showed the aspects of quality of life most affected by the presence of diabetes mellitus were physical capacity and family relationship, due to the presence of symptoms such as discomfort and tiredness. In the WHOQoL, the physical domain is related to aspects such as pain, fatigue, mobility and dependence of medication.[33] The lowest physical score observed in T2DM patients corroborates some data from the literature.[35] Aging is another factor that influences quality of life, particularly the physical domain due to the reduction in muscle strength, flexibility and endurance.[36]

CONCLUSION

In conclusion, the proposed pharmaceutical care program carried out in T2DM improved medication adherence and quality of life. The favorable results can be attributed to the provision of proper education on pharmacological treatment and better communication with patient showing a pharmaceutical care program in primary care may provide contributions to prevent clinical complications.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interests.

AUTHORS ACONTRIBUTION

All authors were involved in the design of the study. Lira-Meriguete A. M. was responsible for the data analysis, interpretation of the results, and writing of the first draft of the manuscript; Santos M. P., Guimaraes, F. C., Viana, V. C. S. and Goncalves, N. A. Z contributed to data collection, data interpretation and critical revision of the manuscript; Ayres, L. R., Bem, D. A. M. G. and Goncalves, R. C. R. supervised the study and corrected the last version of the manuscript; All authors meet the criteria for authorship, take responsibility for the integrity of work and have given approval for the version to be published.

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